CAREONE- benzalkonium chloride soap Retail Business Services, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Benzalkonium Chloride (0.13%)

Purpose

Antibacterial

Uses

Helps eliminate bacteria on hands.

Warnings

For external use only.

When using this Product

• Avoid contact with eyes. In case of contact, rinse thoroughly with water.

Stop use and ask a doctor if

• irritation or redness develops and lasts.

Keep out of reach of children

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- Apply onto wet hands.
- Lather and rinse thoroughly..

Other Information

Store at Room Temperature

Inactive Ingredients

Water (Aqua), Cetrimonium Chloride, Lauramidopropylamine Oxide, Glycerin, Sodium Chloride, Cocamide MEA, PEG-120 Methyl Glucose Dioleate, Citrus Nobilis (Mandarin Orange) Peel Extract, Camellia Sinensis Leaf Extract, Zingiber Officinale (Ginger) Root Extract, Fragrance (Parfum), Citric Acid, Tetrasodium EDTA, Sodium Sulfate, Methylchloroisothiazolinone, Methylisothiazolinone, Yellow 5 (Cl 19140), Yellow 6 (Cl 15985).

PDP03

Front Label



Back Label



ART #:01596	DESIGNER #: KR	NOTE:				
CLIENT: APOLLO	JOB DESCRIPTION: 0	6-24090-91 C	AREONE CITRUS FRE	ESH DATE: JUNE 13, 2019	PROOF# 1	MATERIAL:
THIS IS NOT A COLOUR AC Please refer to process and pantone of Every effort has been made to ensure the a nesuring that label size, copy graphics a Label line, of any discrepancies prior to file Label line, against any liability related to o	CURATE PROOF. COUNTY Of this proof. However, the client of the county are accurate and colour separations are accurate, and colour separations are accurate as a colour separation and colour separations are accurate as a colour separation and colour separations are accurate as a colour separation and colour separations are accurate as a colour separation and colour separations are accurate and colour separations are accurate, and colour separations are accurate and colour separations are accurate accur	resentation.	COLOURS C M Y K PMS 376 DIELINE DOIS NOT PRINT	THE CLIENT IS RESPONSIBLE FOR APPROVING THE FOLLOWING: 1. ALL COPY 2. LABEL DIMENSIONS 3. COLOURS USED 4. REVIND COPY DIRECTION 5. LOCAL, PROVINCIAL OR NATIONAL REGULATIONS ASSOCIATED WITH THIS LABEL(S) APPROVED AS IS: APPROVED WITH CHANGES INDICATED: RE-PROOF DATE:		WHITE BOPP COATING: GLOSS LAMINATE

PLEASE NOTE THAT THERE WILL BE NO LABEL PRODUCTION WITHOUT A SIGNED PROOF. FAX APPROVALS TO 416 321-2267. THANK YOU.

benzalkonium chloride soap

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72476-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	130 mg in 100 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
CETRIMONIUM CHLORIDE (UNII: UC9PE95IBP)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)				
BASIC YELLOW 5 (UNII: 07BP340B4T)				
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
CITRUS NOBILIS (UNII: 8MFF77J91V)				
CAMELLIA SINENSIS FLOWER (UNII: 912BJY2J17)				
COCO MONOETHANOLAMIDE (UNII: C80684146D)				
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)				
ZINGIBER OFFICINALE WHOLE (UNII: IN6Q3S3414)				
FRAGRANCE FRESH CITRUS FLORAL ORC1501495 (UNII: OU4GI2R2WB)				
SODIUM SULFATE (UNII: 0YPR65R21J)				
DIRECT YELLOW 6 (UNII: 9CU9YEE7RC)				
WATER (UNII: 059QF0KO0R)				
EDETATE SODIUM (UNII: MP1J8420LU)				
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)				

Product Characteristics			
Color	Score		
Shape	Size		
Flavor	Imprint Code		
Contains			

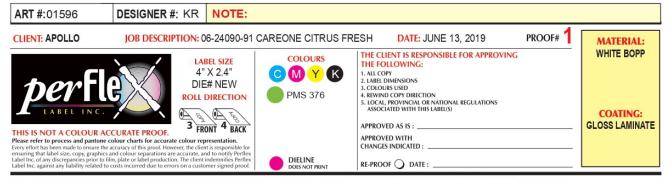
P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72476- 003-03	333 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/26/2021		

Front Label



Back Label





PLEASE NOTE THAT THERE WILL BE NO LABEL PRODUCTION WITHOUT A SIGNED PROOF. FAX APPROVALS TO 416 321-2267. THANK YOU.

Marketing Information

Category	Citation	Date	Date
OTC monograph not final	part333E	08/26/2021	
IIIIai			

Labeler - Retail Business Services, LLC (967989935)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment				
Name	Address	ID/FEI	Business Operations	
Spa Dent Inc		203478896	manufacture(72476-003)	

Revised: 9/2021 Retail Business Services, LLC